

REMARKS

Applicant respectfully requests reconsideration of this patent application, particularly in view of the above Amendment, the accompanying Declaration of Dr. Dinesh-Kumar Patel, and the following remarks addressing the criticality of halting probiotic activity in the composition.

Applicant's claimed invention is a composition which includes at least one DHLA-producing probiotic organism, R-lipoic acid, at least one nutritive agent, dihydrolipoic acid (DHLA), and an effective amount of an agent which halts probiotic activity.

Amendments to the Claims

Claims 4-22 and 24-26 are pending with Claims 13-19 withdrawn. Claims 4-12, 20-22, and 24-26 have been examined with no claims allowed.

Claims 21 and 24 have been amended to clarify that the probiotic organisms are non-viable (i.e., once living). Support is found on: page 1, line 3; page 3, line 8; page 4, lines 18-20; page 5, lines 5, 8, and 12; and original Claims 2 and 3.

No new matter has been added by this Amendment. No additional claim fees are believed to be due because the number of claims currently pending does not exceed the number previously paid for. However, should any fees be required (to maintain the pendency of this application or to timely enter this responsive paper into the file of the above-captioned application) or an overpayment of fees made, the Commissioner is hereby authorized to debit or credit our Deposit Account No. 50-3394, as necessary.

Claim Rejections – 35 USC §103**I. Hastings in view of Niggemann and Biewenga, and in further view of Hermann**

The rejection of Claims 4-10, 20-22, 25, and 26 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,368,617 to Hastings et al. in view of German Patent DE 19730538 to Niggemann, Biewenga et al. (Gen. Pharmac, 1997) and in further view of Hermann et al (European Journal of Pharmaceutical Sciences, 1996) in light of support from Dunne et al. and Mercenier et al. is respectfully traversed.

Applicant's invention as recited in Claims 4 and 21 is a composition including at least one probiotic organism, R-lipoic acid, at least one nutritive agent, dihydrolipoic acid, and an effective amount of an agent to halt probiotic activity in the composition. None of the references of record disclose or suggest such a combination.

Generally, as would be understood by a person having ordinary skill in the art, live microorganisms are included in dietary supplements to confer a health benefit to the host. Hastings, Dunne, Mercenier, and Niggemann all teach or disclose that live probiotic organisms can be ingested by an individual to his/her benefit. Indeed, Hastings discloses dietary supplements which include probiotic organisms for promoting healthy hormone balance and reducing the effects of aging in adult human subjects. In particular, Hastings discloses that a probiotic blend of *Bifidobacterium bifidum* and *Lactobacillus acidophilus*, and the fructo-oligosaccharides, are included in dietary supplement to promote intestinal health by increasing and maintaining intestinal flora (Col. 4, line 66 – Col. 5, line 3). Further Niggemann, similar to Hastings, discloses that the benefit of ingesting fermented beverages such as Kefir is found in the living bacterial cultures (page 1, ¶ 7 of the machine translation) and that the ethanol content of currently available fermented beverages forbids a quantitatively sufficient daily microorganism supply (page 2, ¶ 7 of the machine translation).

There is no motivation for a person of ordinary skill in the art to modify the compositions disclosed in Hastings to include an effective amount of probiotic activity halting agent to halt probiotic activity in the compositions, i.e., stopping or permanently ceasing all probiotic activity in the composition, because such a modification would render the probiotic organisms in the compositions of Hastings, alone or as modified by Niggemann, Biewenga, and/or Hermann, unsuitable for their intended purpose, to reduce the effects of aging such as by promoting intestinal health of a host.

At issue in the present Office Action is the limitation in Claims 4, 21, and 24 requiring “an effective amount of a probiotic activity halting agent to halt probiotic activity in the composition.” The Examiner seeking to give this limitation its broadest reasonable interpretation has construed this limitation as reading on small amounts of probiotic activity halting agents which may only stop probiotic activity for an infinitesimally short period of time (Office Action, page 3). Accordingly, the Examiner maintains that “halting activity” does not equate with “killing or completely deactivating” but only a “suspension of activity” which may or may not be temporary (Office Action, page 6).

Applicant respectfully submits that the context of the Specification demonstrates that the inventor uses the term “halt” (and its correlating term “halting”) to mean a complete and permanent stop, which is an established dictionary definition of the term. As explained more

fully below, any broader definition, so as to include a temporary cessation of activity, is incompatible with the Specification's teaching that the dihydrolipoic acid (DHLA) present in the composition be derived from a "once living" source. Applicant also submits herewith the Declaration Dr. Dinesh Patel to support its contention that one of ordinary skill in the field of this invention would be inclined to interpret the terms "halt" or "halting" in the context of the subject matter of the present invention as indicating a complete and permanent cessation of activity, in contrast with other terms used in the field to indicate an incomplete or temporary cessation of activity.

It is well established that the words of a claim are initially given as broad an interpretation as their terms reasonably allow (*In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004)). Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification (*In re Marosi*, 710 F.2d 799, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) quoting *In re Okuzawa*, 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976)). In construing claim terms, the general meanings gleaned from reference sources, such as dictionaries, are to be compared against the use of the terms in context, and the intrinsic record must be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor (*ACTV, Inc. v. The Walt Disney Company*, 346 F.3d 1082, 1092, 68 USPQ2d 1516, 1524 (Fed. Cir. 2003)). Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meaning and toward the proper meanings (*Renshaw PLC v. Marposs Societa, per Azioni*, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998)).

If read without reference to the Specification and using all allowable definitions, the term "halting probiotic activity" could be broadly read as encompassing "suspension of activity" as suggested on page 6, 2nd paragraph of the Office Action. Several dictionaries, examples of which are attached hereto, include a definition for the word "halt" as meaning a "temporary stoppage" or "suspension of progress." However, these same sources define the word "halt," particularly when used as a transitive verb (as is the case in the present claims), to mean "to bring to a stop," "to cause discontinuation of," or "to end" some activity.

Applicant respectfully submits that it is this latter definition, when the word "halt" (i.e., to stop, terminate, or end) is used as a verb, that applies, particularly when Claims 4 and 21 are read in the context of the Specification. Throughout the Specification, Applicant has made clear

that the dihydrolipoic acid (DHLA) present in the composition is derived from a “once living” (i.e., a currently dead or non-viable) source. See, for example, page 1, line 3; page 3, line 8; page 5, lines 5, 8, and 12; and original Claims 2 and 3. Defining the terms “halt” and “halting” to mean a temporary “suspension of activity” which leaves the probiotic organisms “still live and vital” as suggested (e.g., see, page 6, 2nd paragraph of the Office Action) is inconsistent with the teachings of the Specification as a whole.

It is further contended that Applicant’s position is consistent with how the terms “halt” and “halting” would be construed by a person having ordinary skill in the art at the time the invention was made. In the field of biochemistry and its application to the production of pharmaceutical and dietary supplement compositions, the terms “halt” and “halting” in relation to probiotic activity in a microbiological culture composition such as those recited in Claims 4, 21, and 24 mean a complete and permanent cessation of the probiotic activity within the composition, in contrast to an incomplete or temporary cessation of probiotic activity which would leave at least some of the probiotic organisms viable (Declaration, ¶ 9, 12, and 13). Additionally, one of ordinary skill in the field of biochemistry would use terms other than “halt” for a temporary or incomplete cessation of probiotic activity in the context of the subject matter of the present application, such as “suspend,” “retard,” or “reduce” (Declaration, ¶ 10).

The Examiner has also asserted that he has “searched the Specification for guidance as to the ‘effective amount’ and did not readily find a number or formula explicitly defining what is an “effective amount of agent.” Applicant responds that the Specification of the present application discloses that the amount of agent used to halt probiotic activity is an amount sufficient to end probiotic activity in a given composition. This amount would depend on the probiotic nature of the composition and the number of the probiotic organisms present, as well as the strength of the agent with respect to the agent’s ability to end probiotic activity. Determining the amount of agent necessary to end probiotic activity (i.e., to effectively render the organisms non-viable) is a matter of routine measurement of probiotic activity in the composition and the determination of the amount of agent used can be accomplished without undue experimentation (Declaration, ¶ 15).

In view of the above, Applicant respectfully submits that Hastings in view of Niggemann and Biewenga and in further view of Hermann in light of support from Dunne and Mercenier

does not disclose or suggest a composition including an agent in an amount effect to halt probiotic activity.

For at least the reasons above, Claims 4 and 21 as amended are patentable over Hastings in view of Niggemann, Biewenga, and Hermann. Because Claims 5-10, 20, 25 and 26 depend from Claim 4, and Claim 22 depends from Claim 21, these claims are also patentable over Hastings in view of Niggemann, Biewenga and Hermann. Accordingly, reconsideration and withdrawal of this rejection with respect to Claims 4-10, 20-22, 25, and 26 are respectfully requested.

II. Hastings in view of Niggemann, Biewenga, and Hermann and in further view of Reddy

The rejection of Claims 4-12, 20-22, and 24-26 under 35 U.S.C. § 103(a) as unpatentable over Hastings in view of Niggemann, Biewenga, and Hermann in light of Dunne and Mercenier and in further view of U.S. Patent 6,080,401 to Reddy et al. is respectfully traversed.

As discussed above, Hastings, alone or as modified by Niggemann, Biewenga, and/or Hermann, does not disclose or suggest a composition including an effective amount of an agent which halts probiotic activity. Thus, Claims 4 and 21 are believed to be patentable. Additionally, because Claim 24 also recites a composition including an effective amount of an agent which halts probiotic activity, this claim is also believed to be patentable for the same reasons.

Reddy teaches compositions that include a probiotic blend of *Bifidobacterium* and *Lactobacillus* (Col. 9, lines 33-44) and which can also contain *Curcuma longa* (Col. 8, line 5). Reddy, however, does not overcome the deficiencies of Hastings in view of Niggemann, Biewenga, and Hermann. In fact Reddy further teaches away from the composition recited in amended Claims 4, 21, and 24. Specifically, Reddy requires that the compositions disclosed therein include viable probiotic organisms and that such compositions be free of substances which are substantially inhibitory to the viability of the probiotic organisms for it is the activity of the probiotic organisms that enhances the efficacy of the drug with which it is combined (see, e.g., Col. 6, lines 30-33). Thus, Reddy teaches away from the combination of a probiotic organism, R-lipoic acid, turmeric rhizome, and an effective amount of an agent which halts probiotic activity as recited in Claims 4, 21, and 24.

For at least these reasons, Applicant respectfully submits that Claims 4, 21, and 24 are patentable over Hastings in view of Niggemann, Biewenga, and Hermann and in further view of Reddy. Because Claims 5-12, 20, 25 and 26 depend from Claim 4 and Claim 22 depends from Claim 21, these claims are also believed to be patentable. Accordingly, reconsideration and withdrawal of this rejection as applied to Claims 4-12, 20-22, and 24-26 are respectfully requested.

Conclusion

Applicant believes that the application is now in condition for allowance. If the Examiner feels that any issues remain regarding this application, then Applicant's undersigned attorney respectfully requests a telephone interview with the Examiner to discuss these issues. The undersigned can be reached at (312) 327-3327.

Respectfully submitted,

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hal-yard or hal-lard \hāl-yôrd\ n : October 31 observed especially by children wearing costumes and eating treats and by the displaying of jack-o'-lanterns for *All Hallow even*, the eve of All Saints' Day

hal-mas \hāl-mâs, -mâs\ n : ALL SAINTS' DAY

hal-na-don \hāl-nâd-n, -shon\ n : the perceiving

of the experiencing of feelings that have no

place outside one's mind especially as the result of a

mental disorder or as the effect of a drug; also : some-

thing perceived or experienced [Latin *hallucinatio*,

“a *hallucinari*” “to wander in mind”] — **hal-lu-clu-**

sis \hâl-nâs\ vb — **hal-lu-clu-so-to-ry** \hâl-nâs-

, -râr\ adj

hal-no-gen \hâl-nâj-n, -jan\ n : a substance (as

iodine) that induces hallucinations — **hal-lu-clu-no-gen-ic**

\hâl-nâj-n, -ik\ adj

hal-ak-s \hâl-âk-s, pl **hal-ku-ces** \hâl-âs, -sâz, -yô\ n : BIG

[Latin]

hal-hôl \hâl-wâl\ n 1 : an entrance hall. 2 : CORRIDOR

2 : **hal-hôl** \n, pl **hal-hôles** 1 : a circle of light

around the sun or moon caused by the presence of tiny

crystals in the air. 2 : something resembling a halo:

2 : NUMBS 1, 2 b : a differentiated zone surround-

ing a central object. 3 : the glory surrounding an ideal

and person or thing [Latin *halos*, from Greek *halos*

“threshing floor, disk, halo”]

hal-hôl vt : to form into or surround with a halo

— **hal-hôl** — SEE HALO

hal-ge-gen \hâl-jê-jân\ n : any of the five elements fluo-

rine, chlorine, bromine, iodine, and astatine existing

in the free state normally as diatomic molecules

hal-ge-ton \hâl-jé-tân\ n : a coarse annual herb

related to the goosefoots that is a noxious weed in

western North America [bal- + Greek *getion* “neigh-

ing”]

hal-o-phile \hâl-ô-fîl\ n : a plant that thrives in salty

soil — **hal-o-phyl-ic** \hâl-ô-fîl-ik\ adj

hal-hôl adj : LAME [Old English *hels*]

hal-hôl vt 1 : to walk or proceed lamely. 2 : to

stand in perplexity or doubt between alternate courses. 3 :

to display weakness or fault

hal-hôl n : stop (call a *halt*) [German, derived from Old

High German *halten* “to hold”]

hal-hôl vt 1 : to cease marching or journeying. 2 : to

bring or come to a stop. 3 : END

hal-hôl \hâl-târ\ n 1 : a rope or strap for leading or

tying an animal. 2 : a headstall to which a lead may be

attached. 2 : a rope for hanging criminals. 3 : a

woman's blouse that is typically held in place by

straps around the neck and across the back and leaves

the back, arms, and midriff bare [Old English *halſtre*]

hal-hôl or **hal-tered**; **hal-ter-ing** \hâl-tîr-ing, -trîng\ v : to

catch or as if with a halter. 2 : also : to put a halter

on 2 : RESTRAIN. 1, HAMPER

hal-hôl \hâl-tîr, 'hâl-tîr, 'hâl-hôl\ n : one of a pair of club-

shaped organs that are the modified second pair of

wings of a two-winged fly and serve to maintain

balance in flight [Latin *balter* “jumping weight”, from

[Greek *balter*, from *balles* “to jump”]

hal-hôl-ing \hâl-tîng\ v : marked by a limp. 2 : UNCER-

TAIN, FALTERING (the witness spoke in a halting manner) — **hal-hôl-ing** \hâl-tîng, -îng\ adj

hal-hôl or **hal-hôl** \hâl-hâl, -hâl\ n : a flaky candy

made of crushed sesame seeds in a base of syrup (as of

honey) [Yiddish *halva*, derived from Arabic *halwa*

“sweetmeat”]

hal-hôl \hâl-hâl, 'hâl-hâl\ vt 1 : to divide into two equal parts

2 : to reduce to one half (*halving* the cost). 3 : to share

equally 2 : to play (a hole) in the same number of

strokes as one's opponent at golf

hal-hôl-ers \hâl-hôl-ârz, 'hâl-hâl-n pl : half shares : HALVES

hal-hôl-pi of *HALF*

hal-yard or hal-lard \hâl-yôrd\ n : a rope or tackle for hoisting and lowering [Middle English *halter*, from *halen* “pull, haul”]

ham \hâm\ n 1 : a : a buttock with its associated thigh — usually used in pl. 2 : a cut of meat consisting of a thigh; esp : one from a hog. 3 a : an unskillful but showy performer. b : an operator of an amateur radio station [Old English *hamm* “hollow of the knee”; sense 3 short for *hamfatter*, from “The Ham-Fat Man,” minstrel song] — **ham adj**

ham vb hammed; ham-ming : to execute with exaggerated speech or gestures : OVERACT

ham-a-dry \hâm-a-dri-âd, -âd\ n : WOOD NYMPH [Latin *hamadryas*, from Greek, from *hamâ* “together with” + *dryas* “dryad”]

ham-bur-er \hâm-bar-gâr\ or **ham-burg** \hâm-bârg\ n 1 : a : ground beef. 2 : a cooked patty of ground beef. 2 : a sandwich consisting of a patty of hamburger in a split round bun [German *Hamburger* “of Hamburg”]

hamme \hâm-mâ\ n : one of two curved supports which are attached to the collar of a draft horse and to which the traces are fastened [Middle English]

ham-ite \hâm-it\ n : a member of a mainly Caucasoid group of chiefly northern African peoples [Ham, son of Noah, their supposed ancestor]

ham-it-ic \hâm-it-ik, hâ\ adj : of, relating to, or characteristic of the Hamites or one of the Hamitic languages

Hamitic languages n pl : the Berber, Cushitic, and sometimes Egyptian branches of the Afro-Asiatic languages

ham-let \hâm-lât\ n : a small group of houses in a rural area [Middle French *hamelet*, from *ham* “village”, of Germanic origin]

ham-mer \hâm-er\ n 1 a : a hand tool that consists of a solid head set crosswise on a handle and is used for pounding (as in driving nails). b : a power tool that substitutes a metal block or a drill for the head for pounding (as in driving posts or breaking rock). 2 : something that resembles a hammer in shape or action as a : an implement consisting of a handle or lever and a striking head used to sound a musical instrument (as in the strings of a piano, or a xylophone)

b : the part of a gun whose striking action causes explosion of the charge. 3 : **MAILLEUS** 4 : a metal sphere weighing about 7.26 kilograms that is attached to a wire handle and is hurled in an athletic event [Old English *hamor*]

hammer vb ham-mered; ham-mer-ing \hâm-ring, -îng\ 1 : to strike blows especially repeatedly with or as if with a hammer. 2 a : to make repeated efforts. b : to emphasize (as an opinion) by repetition. 3 a : to beat, drive, or shape with repeated blows of a hammer. b : to fasten or build with a hammer. 4 : to produce or bring about as if by repeated blows (as *ham-mer out a policy*)

hammer and sickle n : an emblem consisting of a crossed hammer and sickle used chiefly as a symbol of Soviet Communism

hammer and tongs adv : with great force and violence

ham-mered adj : having surface indentations produced or appearing to have been produced by hammering

ham-mer-head \hâm-er-hed\ n 1 : the striking part of a hammer. 2 : **BLOCKHEAD** 3 : any of several sharks with the eyes on lateral extensions of the flat head

ham-mer-lock \hâm-lôk\ n : a wrestling hold in which an opponent's arm is held behind the back

ham-mer-toe \hâm-toe\ n : a toe and especially the second deformed by having the end part permanently bent

ham-mock \hâm-môk\ n : a swinging couch or bed usually made of netting or canvas and slung by cords from supports at each end [Spanish *hamaca*, of American Indian origin]

hammock n : HUMMOCK 1 [origin unknown]



hammerhead 3

\hâb\ abut	\hâng\ sing
\hâb\ further	\hâb\ bone
\hâb\ mat	\hâb\ saw
\hâb\ take	\hâb\ coln
\hâb\ cot, cart	\hâb\ thin
\hâb\ out	\hâb\ this
\hâb\ chin	\hâb\ food
\hâb\ pet	\hâb\ foot
\hâb\ easy	\hâb\ yet
\hâb\ go	\hâb\ few
\hâb\ tip	\hâb\ cure
\hâb\ life	\hâb\ vision
\hâb\ job	

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hal-in-cl-no-sa-pa (vba-¹⁵⁻³-n⁶⁻²²) n [NL] (1905) : a pathological mental state characterized by delusions of grandeur, hallucinations, and delusions of guilt; *hal-in-ka-lek-n*, *hal-in-ha* (vba-¹⁵⁻³-n⁶⁻²², "hal-in-ya") [NL, fr. L *halitus*, *halitus*] (1831) : the innermost digit (as the big toe) of a hind or lower limb; *hal-in-vey* [hal-in-wa] (1876) : 1: an entrance hall 2: CORRIDOR; *hal-in-sa* [hal-in-ma] n [Gk, leap, fr. *hallein* to leap — more at SALLY] (1889) : a game played on a square board and having rules similar to those of Chinese checkers

hal-in-ta (hal-in-ta) n [Gk, *halitus*, *halitus*] (1603) 1: a circle of light appearing to surround the sun or moon and resulting from refraction or reflection of light by ice particles in the atmosphere 2: something resembling a halo as a nimbus

hal-in-ti (hal-in-ti) n [Gk, *halitus*, *halitus*] (1889) : a differentiated zone surrounding the sun or moon, or a zone of light, in the sky, glistening, or sentiment surrounding an idealized person or thing

halo (vba-¹⁵⁻³-n⁶⁻²²) 1: to form into or surround with a halo (rainbows ~ed the waterfall) — [Michael Crawford]

halo (vba-¹⁵⁻³-n⁶⁻²²) n [Gk, *halo*] (1950) : a user vertical gradient in salinity (as of the ocean)

halo effect (n. 1928) : generalization from the perception of one outstanding personality to an overly favorable evaluation of the whole group to which it belongs

halo-gen (vba-¹⁵⁻³-n⁶⁻²²) n [Sw, fr. *hal-* + *gen*] (1842) : any of the five elements fluorine, chlorine, bromine, iodine, and astatine that form part of group VII A of the periodic table and enter the free state normally as diatomic molecules

halo-gen-ate (vba-¹⁵⁻³-n⁶⁻²²) n [Sw, fr. *hal-* + *gen* + *-ate*] (1882) : to treat or cause to become surrounded with a halo — *halo-gen-ation* (vba-¹⁵⁻³-n⁶⁻²²)

halo-gen-on (vba-¹⁵⁻³-n⁶⁻²²) n [NL, fr. *hal-* + *gen* (genitor) (neighbor)] (1943) : a coarse annual plant (*Thlaspi glomeratum*) of the goosefoot family that is a noxious weed in western North America

halo-gen-ox-ide (vba-¹⁵⁻³-n⁶⁻²²) n [NL, fr. *hal-* + *gen* + *-oxide*] (1957) : a nonpolarizing inhalational anesthetic $\text{C}_2\text{H}_5\text{ClF}_2$

halo-gen-per-ox-ide (vba-¹⁵⁻³-n⁶⁻²²) n [NL, fr. *hal-* + *gen* + *-per-* + *oxide*] (1957) : an anticonvulsive drug

halo-phyt-e (vba-¹⁵⁻³-n⁶⁻²²) n [NL] (1923) : an organism that flourishes in a salty environment — *halo-phyt-e* (vba-¹⁵⁻³-n⁶⁻²²)

halo-phyt-ic (vba-¹⁵⁻³-n⁶⁻²²) n [NL, fr. *halo-* + *phyt-ic*] (1880) : a plant (as saltbush or sea lavender) that grows in salty soil and has a physiological resemblance to a true xerophyte — *halo-phyt-ic* (vba-¹⁵⁻³-n⁶⁻²²) adj

halo-phyt-on (vba-¹⁵⁻³-n⁶⁻²²) n [NL, fr. *halo-* + *phyt-on* (change) (1957) : a nonpolarizing inhalational anesthetic $\text{C}_2\text{H}_5\text{ClF}_2$

halo-phyt-on (vba-¹⁵⁻³-n⁶⁻²²) n [NL, fr. *halo-* + *phyt-on*] (1943) : an anticonvulsive drug

halo-phyt-on (vba-¹⁵⁻³-n⁶⁻²²) n [NL, fr. *halo-* + *phyt-on*] (1957) : an anticonvulsive drug

halo-ton (vba-¹⁵⁻³-n⁶⁻²²) n [NL, fr. *halo-* + *ton-*] (1957) : to display perplexity or impatience — *halo-ton* (vba-¹⁵⁻³-n⁶⁻²²)

halo-ton (vba-¹⁵⁻³-n⁶⁻²²) n [NL, fr. *halo-* + *ton-*] (1957) : to display perplexity or impatience — *halo-ton* (vba-¹⁵⁻³-n⁶⁻²²)

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